(2) At lower levels in a chronic study than previous studies with similar species.

(3) In a study with a previously untested species the results indicate the chronic no observed effect level (NOEL) is 10 percent or less of the lowest LC_{50} or LD_{50} for a similar species.

(4) For plants when tested at the maximum label application rate or less, if either of the following conditions is met:

(i) More than 25 percent of terrestrial plants show adverse effects on plant life cycle functions and growth such as germination, emergence, plant vigor, reproduction and yields.

(ii) More than 50 percent of aquatic plants show adverse effects on plant life cycle functions and growth such as germination, emergence, plant vigor, reproduction and yields.

(c) Results from a study that demonstrates any toxic effect (even if corroborative of information already known to the Agency), must be submitted if the pesticide is or has been the subject of a Formal Review based on that effect within 5 years of the time the results are received. Within 30 calendar days of the publication of a Notice of Commencement of a Formal Review in the FEDERAL REGISTER, all information which has become reportable due to the commencement of the Formal Review must be submitted.

(d) *Incomplete studies.* Information from an incomplete study of the toxicity to any organism of a registered pesticide product or any of its ingredients, impurities, metabolites, or degradation products which would otherwise be reportable under paragraphs (a), (b) or (c) of this section must be submitted if the information meets any one of the folowing three sets of criteria:

(1) *Short-term studies.* A study using a test regimen lasting 90 calendar days or less, and all of the following conditions are met:

(i) All testing has been completed.

(ii) A preliminary data analysis or gross pathological analysis has been conducted.

(iii) Final analysis has not been completed.

(iv) A reasonable period for completion of the final analysis not longer than 90 calendar days following completion of testing has elapsed.

(v) Comparable information concerning the results of a completed study would be reportable.

(2) *Long-term studies.* A study using a test regimen lasting more than 90 calendar days, and all of the following conditions are met:

(i) All testing has been completed.

(ii) A preliminary data analysis or gross pathological analysis has been conducted.

(iii) Final analysis has not been completed.

(iv) A reasonable period of completion of final analysis (not longer that 1 year following completion of testing) has elapsed.

(v) Comparable information concerning the results of a completed study would be reportable.

(3) *Serious adverse effects.* Any study in which testing or analysis of results is not yet complete but in which serious adverse effects have already been observed which may reasonably be attributed to exposure to the substances tested, because the effects observed in exposed organisms differ from effects observed in control organisms, are atypical in view of historical experience with the organism tested, or otherwise support a reasonable inference of causation, and 30 days have passed from the date the registrant first has the information.

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998; 73 FR 75597, Dec. 12, 2008]

§ 159.167 Discontinued studies.

The fact that a study has been discontinued before the planned termination must be reported to EPA, with the reason for termination, if submission of information concerning the study is, or would have been, required under this part.

§ 159.170 Human epidemiological and exposure studies.

Information must be submitted which concerns any study that a person described in §159.158(a) has concluded, or might reasonably conclude, shows that a correlation may exist between exposure to a pesticide and observed adverse effects in humans. Information must also be submitted which concerns